

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D-0320]

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Certifier A. Corbin

**Guidance for Industry and Clinical Investigators on the Use of Clinical Holds
Following Clinical Investigator Misconduct; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry and clinical investigators entitled "The Use of Clinical Holds Following Clinical Investigator Misconduct." This guidance provides information on FDA's use of its authority to impose a clinical hold on a study if FDA finds that a clinical investigator conducting the study has committed serious violations of our regulations pertaining to clinical trials involving human drug or biological products or has submitted false information to FDA or to the study's sponsor in any report. The guidance is intended to inform interested persons of the circumstances in which we may impose a clinical hold following the discovery of a clinical investigator's misconduct and the steps we might take to protect human subjects from investigator misconduct.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD

20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Rachel Behrman, Center for Drug Evaluation and Research (HFD-40), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301-594-6758; or Patricia Holobaugh, Center for Biologics Evaluation and Research (HFM-664), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6347.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and clinical investigators entitled "The Use of Clinical Holds Following Clinical Investigator Misconduct." The guidance provides information on one use of our authority to impose a clinical hold on a study or a study site if FDA finds that human subjects are or would be exposed to an unreasonable and significant risk of illness or injury. The guidance describes the circumstances in which FDA may impose clinical hold based on credible evidence that a clinical investigator conducting the study has committed serious violations of

our regulations pertaining to clinical trials involving human drug or biological products or has submitted false information to us or to the study's sponsor in any required report. The guidance is intended to inform interested persons of the circumstances in which we may impose a clinical hold following the discovery of a clinical investigator's misconduct and the steps we might take to protect human subjects from investigator misconduct.

In the **Federal Register** of August 27, 2002 (67 FR 55025), FDA announced the availability of a draft version of the guidance entitled "The Use of Clinical Holds Following Clinical Investigator Misconduct." The August 2002 guidance gave interested persons an opportunity to submit comments through November 25, 2002. All comments received during the comment period have been carefully reviewed and, where appropriate, incorporated in the guidance. As a result of the public comments and editorial changes, the guidance is clearer than the draft version.

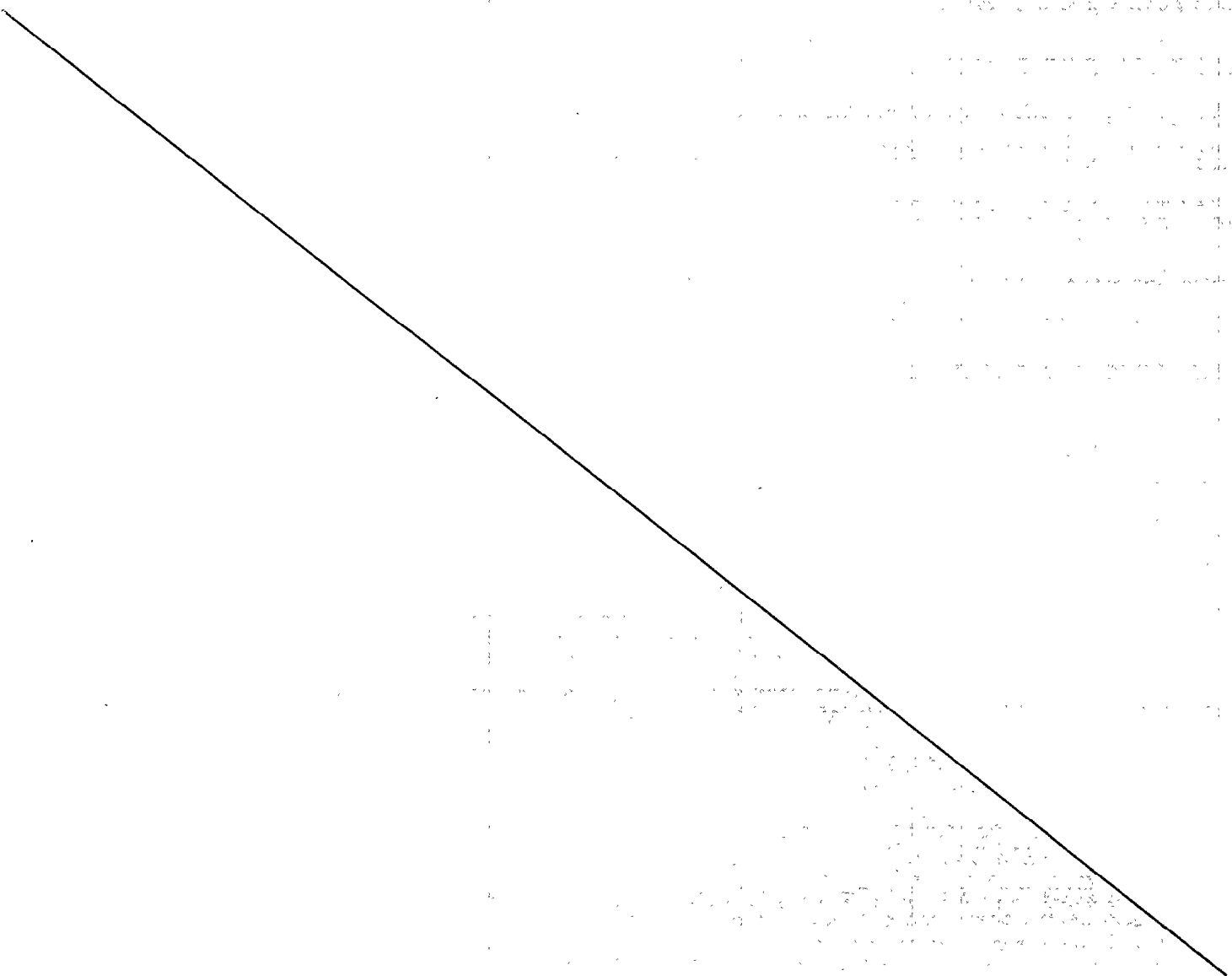
The guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance were approved under OMB control number 0910–0014.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the use of clinical holds to protect human subjects following clinical investigator misconduct in a clinical trial of a human drug or biological product. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. As with other guidance documents, we do

not intend this document to be all-inclusive, and we caution that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

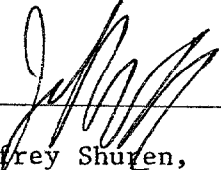
Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments on the guidance at any time. Two paper copies of mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cber/guidelines.htm>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/oc/gcp/guidance.html>.

Dated: 8/23/04
August 23, 2004.


Jeffrey Shuren,
Assistant Commissioner for Policy.

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